

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Truels Stern LARSEN, et al.

Group Art Unit: 3764

Serial No.: 09/926,293

Examiner: Michael A. Brown

Filed: October 9, 2001

For: PRESSURE RELIEVING DRESSING

DECLARATION OF TRUELS STERN LARSEN

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Truels Stern Larsen, do hereby declare the following:

1. I reside in Frederiksberg, Denmark, am currently employed by Coloplast A/S in Humlebaek, Denmark, as a research and development engineer, and am one of the named inventors for the above-captioned application.

2. My educational background is set forth on my Curriculum Vitae ("CV") attached hereto as Attachment A. As indicated, I have a Master of Science degree in Chemistry from Danish Technological University.

3. My professional experience, which is also set forth on the attached CV, Attachment A, includes over twelve years of experience in polymer research and development, eight of which have been in the wound care business. As a result of my education and experience, my

professional contemporaries and colleagues consider me an expert in the field of medical dressings designed to handle wound healing and exudate, as well as dressings and materials having pressure-relieving characteristics. The combination of a dressing for wound treatment and for pressure distribution is especially important for pressure sores that have arisen from dynamic pressure impacts such as for persons suffering from diabetic ulcers.

4. Based upon my education and experience, I have an opinion regarding what the level of ordinary skill would be in the field of medical dressings for wound management and pressure distribution. Persons of ordinary skill in this art would include not only those individuals skilled in the area of wound care and treatment, but also those concerned with pressure distribution materials and configurations in order to prevent and/or facilitate the healing of wounds and pressure sores occurring in areas subject to permanent (static) and/or short term (dynamic) pressure. In most cases, such a person would have a Master of Science degree in chemistry, with several years of experience in the wound care area.

5. I have reviewed the prior art considered by the Examiner, specifically U.S. Patent No. 5,939,339 to Delmore et al. ("Delmore") and WO 93/01777 to Malloul, in the above-captioned application.

6. Drawing upon my expertise in this industry, I understand the level of ordinary skill in the art at the time the above-captioned application was filed (October 9, 2001) and can offer my expert opinion as to how persons of ordinary skill in the art would

have perceived and responded to the cited art at that time.

7. Prior to my invention, it was known in the dressing art to apply pressure to certain types of wounds in order to reduce bleeding and facilitate healing. Conversely, wounds actually caused by undue or long term pressure must be handled differently, needing not the application of pressure but rather a pressure distributing construction to relieve the injured area.

8. Delmore describes an elastic bandage of the pressure applying type, being designed to apply a compressive force when wrapped around an injury. In no way can such a compressive or pressure-applying construction be interpreted to constitute a pressure distributing element. Nor does the material used in the Delmore bandage function to relieve both static pressure and sudden impacts by directing force from the same away from the wound, as is claimed by my invention. Instead, if the bandage of Delmore were fitted, for example, to a patient's heel, no shock-absorbing effect would be achieved during walking.

9. Malloul is a non-elastic wound dressing having two spaced side members for dynamic shock absorption that, through their relative stiffness, provide a raised protective support over the wound. An absorbent element is positioned in the area between the side members so as to remain spaced away from the wound such that the absorbent element does not constitute part of the dressing's skin-contacting surface.

10. Persons skilled in the art would not be motivated to

modify Delmore with the teaching of Malloul, as these two wound dressing types are for completely different purposes. In Delmore, the compression force depends upon the uniform application of pressure created by extending the elastic substrate. An interruption in the continuity of the substrate, such as by inseting an absorbent element therein, would negate the uniformity of this pressure applying function. Malloul, on the other hand, is designed to be inelastic so as to maintain a fixed spacing between the shock absorbing side members to protect the wound without touching it. Changing the padded area so as to bring it into contact with the skin would be contradictory to the express purpose of Malloul, namely to prevent contact with the wound. Therefore, modifying either of these bandage types to incorporate the features of the other would destroy the functionality of both. Hence, in my opinion a person of ordinary skill in the art would not consider combining the teaching of Malloul with that of Delmore.

11. Even if Delmore and Malloul were combined, the result would not correspond with my invention as set forth in claim 1 of the above-captioned application. Malloul shows an absorbent element spaced from the wound and extending between two adjacent pads; Malloul does not teach an absorbent element that forms part of the skin-contacting surface and which extends into the thickness of a pressure distributing element so as to be inset therein. It must follow, therefore, that modifying Delmore to incorporate Malloul would result in two spaced portions of elastomeric substrate joined

by an absorbent element. Such a result would be completely unacceptable from the perspective of Delmore as there would no longer be an even application of compression to the underlying area due to the intervening, non-compressive absorbent element. And even if the elastomeric substrate were to remain unitary with the absorbent element inset therein (a combination for which the skilled person would find no suggestion in the art), the insetting of the absorbent element in accordance with my invention would still alter the uniformity of the resulting compressive force exerted by the Delmore substrate.

12. The fact that my invention is not obvious is substantiated by the continuing absence in the field of a suitable pressure relieving wound dressing. This absence is documented in an article by Carine H. M. van Schie, et al., entitled "Reduction of plantar pressure using a prototype pressure-relieving dressing; Clinical Care/Education/Nutrition" (hereinafter "the van Schie article").

13. The van Schie article reports the results of a study conducted with the participation of eighteen diabetic patients with peripheral neuropathy and peak plantar pressure of greater than 500 kPa. The extent to which plantar pressure was reduced by a pressure relieving dressing (PRD) of a type corresponding with that claimed in the above-captioned application was the subject of the study. The van Schie article was published by LexisNexis on September 1, 2005, and is attached hereto as Attachment B.

14. As stated in the first paragraph of the van Schie article,

"The incorporation of pressure-relieving properties in a wound care dressing for the treatment [of] foot ulcers is a new and interesting concept, although currently there is no dressing available that contains specific pressure-relieving qualities."

15. The PRD tested in the study provided a 30% pressure reduction in the patients tested (see the second paragraph on page 2 of the article). While this study, which was limited to patients without active foot ulceration, did not include testing of the absorbent element specifically, it is clear that the presence of the absorbent element as inset within the pressure distributing element in accordance with the claimed invention, did not compromise the pressure reducing effectiveness of the dressing. As stated in the penultimate paragraph of the van Schie article, "In conclusion, the results of this study have shown the efficacy of a novel pressure-relieving dressing to reduce pressure at individual metatarsal heads in patients at risk of diabetic foot ulceration."

16. The need to relieve pressure when treating diabetic foot ulcers is well known (see the first sentence of the van Schie article). It is also known that wounds such as foot ulcers must be treated with a wound dressing to prevent infection and facilitate healing. Yet despite these ongoing needs, a solution that combines a wound dressing with effective pressure distribution has heretofore not been found, attesting to the novelty and contribution of my invention over the prior art.

17. It is my opinion, therefore, that the subject matter of my

invention as claimed in the above-captioned application would not have been obvious to one of ordinary skill in the art at the time the invention was made, from the prior art cited and considered by the Patent Examiner, or from any other prior art dressing known to me.

18. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

15/12 2005

Date

Truels Stern Larsen

Truels Stern Larsen

Attachment A: CV of Truels Stern Larsen

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Name: Truels Stern Larsen
Address: Holger Danskes Vej 42, lej. 22
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Employment:

1997-2005 Coloplast A/S, Humlebaek, Denmark as R&D Engineer in
Wound Care Department.
1993-1997 Grundfos A/S, Bjerringbro, Denmark as Polymer Chemist

Education

1992 M.Sc Engineer in chemistry at Danish Technological University,
Lyngby, Denmark
2005 Diploma in Engineering Business Administration, Ingenior
Hoejskolen in Ballerup, Ballerup, Denmark

Publications

none

Patents

WO03055536 A Wound Care Device
WO03068283 A Wound Care Device
WO04110511 A Wound Care Device



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Reduction of plantar pressure using a prototype pressure-relieving dressing; Clinical Care/Education/Nutrition

van Schie, Carine H.M.; Rawat, Farooq; Boulton, Andrew J.M.

It is accepted that pressure relief is among the most important aspects in treating diabetic foot ulcers. Clinically, a variety of off-loading devices are used to redistribute pressure away from the area of ulceration to improve wound healing. The incorporation of pressure-relieving properties in a wound care dressing for the treatment foot ulcers is a new and interesting concept, although currently there is no dressing available that contains specific pressure-relieving qualities.

We therefore aimed to investigate the efficacy of a prototype pressure-relieving dressing (PRD) designed to off-load pressure under individual plantar metatarsal head areas. To establish the pressure-reducing efficacy, the PRD was investigated in patients with intact feet only.

RESEARCH DESIGN AND METHODS—The study had institutional review board approval, and all participants gave informed consent. Eighteen diabetic patients with peripheral neuropathy but without active foot ulceration were recruited from the Manchester Diabetes Centre. Other inclusion criteria were peak plantar pressure >500 kPa and no peripheral vascular disease.

Participants visited the gait laboratory on 3 consecutive days. Dynamic plantar pressures were measured during barefoot walking using the optical pedobarograph (1). Following baseline plantar pressure measurement on day 1, the metatarsal head with the highest plantar pressure was covered with the prototype PRD, after which pressure measurement was repeated. The center of the dressing pad was applied over the bony prominence of the target metatarsal head with the pressure-relieving cushion surrounding the target metatarsal head. On day 2, plantar pressures of both feet were measured. On day 3, plantar pressures of both feet were measured and were measured again after the PRD was removed.

The PRD tested was a sterile dressing with combined absorbing and pressure-relieving properties designed especially for Wagner grade I or II diabetic foot ulcers. The dressing design permits the wound area to be covered by the absorbing part of the small nonadhesive dressing pad. The pressure-relieving part is formed in a U-shape around the dressing pad and placed on the intact skin. The pressure-relieving part is made of transparent silicone with a built-in "woven-tread" to maintain shape and thickness and has an average thickness of 4 mm.

All participants were issued a pedometer on the 1st and 2nd day (Touchpad Pedometer 347; Sportline, Yonkers, NY), and the number of steps taken in each 24-h period was measured. For the statistical analysis, a paired t test was used to assess the difference in plantar pressure ($\alpha = 0.05$).

RESULTS—The 18 patients were predominantly male ($n = 15$) with type 2 diabetes ($n = 12$), age 69.1 [\pm or $-$] 9.0 years (means [\pm or $-$] SD) and diabetes duration 20.4 [\pm or $-$] 12.0 years.

Half of the dressings were placed at the second metatarsal head ($n = 9$), with 22% ($n = 4$) on the first and third metatarsal head and one on the fifth metatarsal head. A mean pressure reduction of 30% was observed at the dressing site (817.2 [\pm or $-$] 139.3 vs. 573.2 [\pm or $-$] 166.1 kPa, $P < 0.0001$) (Fig. 1). A significant pressure reduction of 26% was maintained over the next 2 days ($P < 0.0001$). Mean pressure returned to baseline levels once the PRD was removed (764.3 [\pm or $-$] 177.3 kPa). The metatarsal head medial and lateral to the PRD showed a mean pressure reduction of 16% (491.5 [\pm or $-$] 192.3 vs. 410.5 [\pm or $-$] 188.9 kPa and 439.3 [\pm or $-$] 54.5 vs. 370.0 [\pm or $-$] 91.7 kPa, respectively, $P < 0.05$), with a 20% pressure reduction at day 2. There was no change in peak pressure at the control metatarsal head (601.8 [\pm or $-$] 184.7 at day 1 vs. 599.1 [\pm or $-$] 169.3 kPa at day 2).

[FIGURE 1 OMITTED]

The average number of steps taken per day was 6,849.8 [\pm or -] 3,610 (range 1,146-13,384). There was no relation between the percentage of pressure reduction and the average number of steps taken ($r = 0.16$, $P = 528$).

CONCLUSIONS--We demonstrated a 30% pressure reduction by the prototype PRD at individual metatarsal head sites. The limitation of this study was that the pressure-reducing efficacy of the PRD was only tested on intact feet and that foot pressures were only measured using a pressure plate and not inside participants' footwear. However, a strength of this study was that pressure-relieving quality was measured on 3 consecutive days.

A mean pressure reduction of 30% compares well with other protective shoes or off-loading techniques as evaluated with both pressure plate and pressure in-shoe devices (2-7). The prototype dressing was not only effective at reducing pressures at the target metatarsal head, but also at neighboring metatarsal heads. However, there was no pressure redistribution to other foot regions as other areas showed no increase in pressure. This suggests that the PRD would be ideal for patients with high pressure at individual metatarsal heads, in contrast to other usually more "bulky" off-loading devices. Therefore, in addition to foot ulcer treatment, this type of dressing could also have a role in preventative treatment where individual high-risk metatarsal head sites can be identified and targeted with minimal changes to the patient's lifestyle.

The prototype PRD reduced pressure over at least 2 days, with no drop in pressure relief after the 1st day and no relation to level of activity. Felted-foam dressings have also proven to be effective in pressure reduction for 3 days in diabetic patients with neuropathic foot ulcers (8). It is expected that the PRD would effectively reduce pressure for at least the same duration; however, if used in patients with active foot ulceration or as a protective measure, it is recommended to change the dressing at least every 3 days.

It is clear that the pressure-relieving effect of a dressing can only be minor compared with other more traditional offloading techniques. For the same reason, the PRD is not intended as an alternative, but as a supplement to existing devices. The PRD could, for example, be suitable in cases where the patients do not accept special shoes or insoles to assure pressure relief when shoes are taken off, in cases where minor off-loading is necessary, or for preventative and protective purposes.

In conclusion, the results of this study have shown the efficacy of a novel pressure-relieving dressing to reduce pressure at individual metatarsal heads in patients at risk of diabetic foot ulceration. The pressure relief was maintained over 2 days. The effectiveness of pressure-relieving dressings in patients with active foot ulceration needs to be evaluated in future studies.

Acknowledgments--We thank Coloplast (Humlebaek, Denmark) for supplying the prototype pressure-relieving dressings for this study.

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Abbreviations: PRD, pressure-relieving dressing.

A table elsewhere in this issue shows conventional and Systeme International (SI) units and conversion factors for many substances.

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